REMARKS/ARGUMENTS

In the Office action dated November 15, 2005, the Examiner rejected claims 44-55, all of the claims in the Application, under 35 U.S.C. § 103(a) as being unpatentable over U. S. Patent No. 3,799,147 to Adolph *et al.* The Examiner also noted a missing reference to a co-pending Application in paragraph 0026. That missing serial number is provided in the Amendment to the Specification.

In the Specification, paragraph 0026 is amended.

In the Claims, claims 44, 51 and 55 are amended; claims 48 and 49 are cancelled.

The Invention

The invention provides a system and method for detecting heart sounds, and specifically for detecting those heart sounds identified as S1 (beginning of ventricular systole - closure of atrioventricular valves), S2 (beginning of diastole - closing of semilunar valves between aorta and pulmonary artery), S3 (early diastolic period - distention of ventricular wall) and S4 (end of atrial contraction). An analysis of these heart sounds may be used in diagnosis of cardiac disease. It has been established that while S1 and S2 are easily detected, S3, which may indicate congestive heart failure and S4, which may indicate hypertension, acute myocardial infarction or coronary artery disease, are not easily detected by convention means, including stethoscopic examination and convention ECG.

The invention divides heart sounds, gathered by a microphone, into frequency bands. The heart sounds in one or more frequency bands are then identified and displayed in a window in which a heart sound for one of heart sounds S1, S2, S3 and S4 is expected to be

located. As S1 and S2 are generally assumed to be present, the invention is primarily directed towards the detection of heart sound S3 and S4, which, if present, may indicate a form of heart disease.

The Applied Art

U.S. Patent No. 3,799,147, granted March 26, 1974 to Adolph *et al.* is applied as a 35 U.S.C. § 103(a) reference. '147 does in fact filter heart sounds into a number of frequency bands in an attempt to detect myocardial infarction. While not stated in the '147 Specification, it is assumed, from the time frame of the '147 reference, that "photographic recorder 26" is some form of cathode ray tube or a conventional strip chart. In any event, a visual output of the various sound frequency bands and ECG date is provided. What is sought is a shift in the frequency components from the usual 30-50 CPS band to the 20-40 CPS band, which is alleged to be an indication of a myocardial infarction. Col. 7, lines 42-65.

The Claims

While, as stated in the Specification, para 0002, myocardial infarction is one form of heart disease which may be detected by the invention, there are many other maladies which are also detectable by the invention. Independent claims, 44, 51 and 55, have been amended to clarify that the heart sounds which are detected are S1, S2, S3 and S4. There is no teaching nor suggestion that all of these sounds are detected or used by the applied art. The reference merely filters the frequency band of the heart sounds to look for shifts between frequency bands ('147, col. 7, lines 42-65). The instant invention, having split the heart sounds into frequency bands, analyses the sounds in each frequency band to determine if the heart sound is present where it is

expected to be. This feature of the invention is further defined in claim 45, which requires, for an abnormal heart sound, that the amplitude is not the same as that for a normal heart sound. This is quite different from the method of the invention of the applied reference, which looks for a shift in heart sounds between frequency bands, rather than looking at a difference in amplitude between a normal heart sound in a frequency band and an abnormal heart sound *in the same frequency band.*

Referring now to specific claims, claim 44 requires that the heart sounds being detected are heart sounds S1, S2, S3 and S4. As originally filed, claim 44 requires the defining of a window and classification of each beat based on the characteristics of the filtered sound within a window. Although '147 may appear to meet these requirements, there is no teaching nor suggestion of the use of heart sound S1, S2, S3 and S4, nor is the "window" of '147 defined within each beat of the sound data where the heart sound *is expected to be located*: '147, as previously noted, looks for a shift in predominant heart sounds *between* "normal" frequencies and "abnormal" frequencies, which clearly means that, assuming there is a "window" in '147, the sound would be in a different window, associated with a different frequency band. Although the Examiner contends that the "automatic" analysis function of Applicants may be performed by "manual" activity, this is contrary, in this case, to the real-world situation. As stated in para 0003 of the instant Specification, doctors in fact cannot consistently detect S3 and S4 sounds without additional automated help, which is the purpose of the invention herein. Additionally, as '147 does not provide anything near to Applicants' definition and classification components, it is not possible for '147 to perform the analysis required by Applicants' invention, as contended by the Examiner on page 4 of the Office action. The components of '147 may be capable of sensing the

hearts sounds as taught by Applicants, however, '147 does not have the capability to analyze the heart sounds as required by the claims, nor does it have the capability to produce the resultant analysis. The statement that the features of Applicants' invention are obvious is made only after the Examiner has read Applicants' teaching. There is no legitimate way to leap from the '147 disclosure to Applicants' claims without using Applicant's teachings, and this, the Examiner may not do. Claim 44 is clearly allowable over the applied art.

Claim 45 bases heart sound analysis on a reference amplitude. '147 does not teach nor suggest such an analysis, as '147 looks for a shift in a particular sound between frequency bands. Claim 45 is allowable as originally filed.

Claim 46 is allowable because there is no teaching nor suggestion in '147 that an individual heart each beat is classified as invalid, not having the heart sound, possibly having the heart sound, or probably having the heart sound: if a heart sound is not present in '147, it does not appear on the output display. Although there are a number of protocols described in '147 for determining erroneous (invalid) data, there is no way that '147 can determine "possibly" or "probably." '147 is a present or not present system.

Claim 47 requires further analysis of the "possibly" or "probably" criteria, which is not present in '147. Claim 47 is allowable as originally presented.

Claim 50 is allowable with its allowable parent claim.

Claim 51 has been amended to recite heart sounds S1-S4, and to include the limitations of originally presented claim 45, and is allowable for the reasons set forth in connection with claims 44 and 45.

Claim 52 requires that the location of a heart sound within a beat be determined. As there is no discussion of specific heart sounds in '147, '147 cannot teach nor suggest this feature of the invention. As '147 provides an output in pure graphical, frequency-based form, there is no indication of how '147 could make the determination required by claim 52, which is allowable over the applied art.

Claim 53 requires that the location of the heart sound relative to beat be displayed. Again, it is not understood how '147 could possibly meet this limitation, as '147 cannot make the initial determination (claim 52), and cannot meet the limitation of indicating the location of the heart sound relative to a beat. At best, '147 can display a graphical representation of a composite heart sound and the heart sounds split into the frequency bands. Claim 53 is allowable over the applied art.

Claim 54 is allowable with its allowable parent claim.

Claim 55 has been amended to recite heart sounds S1 - S4. Again, '147 is applied as a 35 U.S.C. § 103(a) reference. '147 displays heart sounds, both in composite and frequency bands, and an ECG, and it filters the heart sounds into frequency bands, but does not teach nor suggest use of heart sounds S1 - S4 in any of the frequency bands. Further, '147 does not apply a temporal window and analyze the band information in a window. '147 looks for a shift of heart sounds between frequency bands, and provides some limited analysis to determine whether the heart sound data is valid. Finally, '147 is not capable of indicating the presence or absence of a selected heart sound. As previously noted, it is unlikely that a doctor viewing the output data of '147 would be able, accurately, to determine the presence of S3 or S4 heart sounds. Claim 55 is

allowable over the applied art.

In light of the foregoing amendment and remarks, the Examiner is respectfully requested to reconsider the rejections and objections state in the Office action, and pass the application to allowance. If the Examiner has any questions regarding the amendment or remarks, the Examiner is invited to contact the undersigned.

Provisional Request for Extension of time in Which to Respond

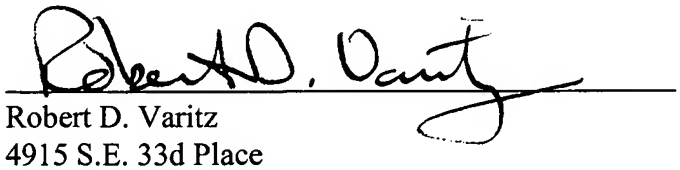
Should this response be deemed to be untimely, Applicants hereby request an extension of time under 37 C.F.R. § 1.136. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any over-payment to Account No. 22-0258.

Customer Number

56703

Respectfully Submitted,

ROBERT D. VARITZ, P.C.



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I hereby certify that the attached Response to Office Action under 37 C.F.R. § 1.111 is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to:

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
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